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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,178	01/13/2004	Fred H. Burbank	R0367-00702	2089

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Edward J. Lynch  
DUANE MORRIS LLP  
One Market  
Spear Tower, Ste. 2000  
San Francisco, CA 94105

EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/756,178

Applicant(s)

BURBANK ET AL.

Examiner

Michael Peffley

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 19, 20 and 22-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 19, 20 and 22-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 6/22/06; 10/5/06.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

Applicant's amendments and comments, received July 21, 2006, have been fully considered by the examiner. In particular, it is noted that applicant has removed the priority claim to several of the previously filed applications/patents. The following is a complete response to the July 21, 2006 communication.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the device having a tissue separator/isolator, an encapsulation means and a damaging means must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

Art Unit: 3739

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 20 and 25-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The application, as originally filed, failed to disclose the specific combination of steps including separating a tissue specimen, encapsulating the separated tissue and damaging the separated tissue specimen as now set forth in independent claim 19. Also, the specification does not disclose a device including separate tissue cutting, tissue encapsulating and tissue damaging devices as now set forth in independent claim 30.

While the instant specification has been amended to include subject matter from related US Patent No. 6,344,026 directed towards a tissue encapsulation device, there is nothing in the instant disclosure or any of the other related documents to support the cutting/separation, encapsulation and damaging of tissue. The instant specification as originally filed (i.e. without the subject matter of the '026 patent incorporate therein) discloses only the cutting/separation of tissue with the subsequent damaging of the

tissue. Page 10 of the specification indicates that Figure 6 shows a "tissue specimen isolating and damaging device" that has a morcellator to morcellate tissue. The specification then states "The tissue specimen may be morcellated after encapsulation of the tissue specimen." This is the only support found that suggests that all three modalities (i.e. separation, encapsulation and damaging) may be performed in the same procedure. However, there is no specific description of how the encapsulation is performed using the tissue isolating and damaging device as shown in Figure 6. The tissue encapsulation device of Figures 9 and 10 fails to disclose a tissue separating and/or tissue damaging means. It seems the only logical way to provide the three separate treatment modalities based on applicant's disclosure would be to insert the device of Figure 6 to isolate/cut tissue, remove that device, insert the device of Figure 9 to encapsulate the tissue, remove that device, then re-insert the Figure 6 device to morcelate/damage the tissue. However, there is no disclosure of such a series of steps, and it seems counterintuitive to the process that allows for the treatment and removal of biopsy tissue with a single device.

It is noted that other related US Patents, such as US Patent No. 6,331,166, indicates that encapsulation of tissue is an alternative treatment to the isolation and damaging of tissue (see Abstract). Also, US Patent No. 6,344,026, which is the subject matter incorporated into the instant specification to provide support for the encapsulation embodiments of Figures 9 and 10, does not disclose the isolation and/or damaging of tissue as now recited in the instant application claims. There is no suggestion in the instant application description or in any of the related applications and

patents that all three modalities (isolation, encapsulation and damaging) are performed in the same procedure with the same device.

It is further noted that US Patent Numbers 6,659,105 and 6,676,658 (from which the instant application is a direct continuation) suggest alternative embodiments where "the tissue specimen is damaged by encapsulation" or "the tissue may be physically isolated by encapsulation". This recitation merely implies that two modalities are one and the same, and does not provide explicit support for performing three separate steps with three separate means as is now recited in claims 19-21 and 25-39.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Kresch et al (5,527,331).

Kresch et al provide a device for isolating and damaging a tissue specimen. The device is inserted into tissue, and a wire cutting element (202 – Figure 9) is used to isolate tissue. The tissue is then damaged by morcellator (206). The arcuate cutting element (202) is also an RF electrode (col. 10, lines 50+).

Claims 1 and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Savage et al (6,032,673).

Figure 9 of the Savage et al device is identical to the above discussed Kresch et al system. It includes an arcuate, RF electrode loop (202) for isolating tissue and a rotating morcellator (206) to damage the tissue.

Claims 1, 19, 20 and 22-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Burbank et al (6,344,026).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicant has removed this reference from the priority claim thereby making this reference available as prior art under 35 USC 102(e). This reference is substantially identical to the device of the instant application and applicant relies on the incorporation by reference of subject matter from the '026 patent to support the claims in the instant application.

### ***Response to Arguments***

Applicant's arguments filed July 21, 2006 have been fully considered but they are not persuasive.

With regard to the newly added figure, the examiner maintains that this figure does not show the three distinct elements set forth in the claims, namely the separating means, the encapsulating means and the damaging means. There is no mention whatsoever of an encapsulation means in the newly added subject matter describing newly added Figure 11. There is also no discussion of a damaging means, and it appears as though the cutting member is used to separate (i.e. isolate tissue).

Concerning the 35 USC 112, first paragraph rejection, the examiner maintains that applicant has not sufficiently shown support for all three of the aforementioned elements in a single embodiment. That the instant disclosure, as well as the disclosures of the related applications/patents, makes mention of the three elements is not disputed. However, as addressed in the rejection, it is not clear what is the distinction of a separating means, or an isolation means, or an encapsulating means. The specification and the related application/patent specifications seem to use these terms interchangeably and there is no clear distinction as to what elements are used to perform these different functions. It is the examiner's position that applicant is piecing together portions of the specification that make mention of these different elements, but that the specification as a whole fails to clearly and expressly disclose a single embodiment which includes a tissue separator (or isolator), an encapsulating device and a damaging device.

Further, it is noted that applicant's removal of the claim for priority to several of the earlier applications/patents has given cause for the Burbank et al (6,344,026) reference to be applied as prior art under 102(e).



With regard to the rejection involving the Kresch et al reference, applicant contends that there is no suggestion of damaging the tissue specimen with a damager located at the distal operational portion. The examiner disagrees. As clearly shown in Figures 9 and 10, a tissue cutter (202) cuts and isolates tissue, and a morcellator (206) adjacent the cutting wire is used to morcellate, or damage, the isolated tissue.

Applicant also contends that the Savage reference fails to disclose this combination of elements, and again the examiner disagrees. Figure 9 of the Savage reference is identical to the Kresch et al Figure 9 and shows the same tissue cutter/isolator (202) and damaging device (206) for damaging the cut tissue specimen.

Applicant's terminal disclaimer is acceptable and has obviated the double patenting rejections.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

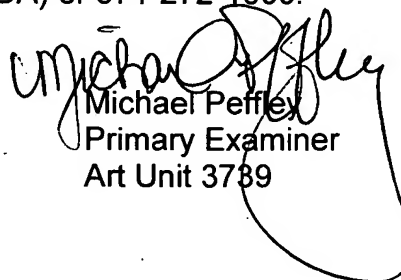
Art Unit: 3739

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Michael Peffley  
Primary Examiner  
Art Unit 3739

mp  
October 27, 2006